

In re the Application of: DONALD K. JONES et al.

Serial No.: 09/880,506

For: OCCLUDING VASCULATURE OF A PATIENT USING EMBOLIC COIL WITH

IMPROVED PLATELET ADHESION

To: Commissioner for Patents P.O. Box 1450

Filed: June 13, 2001

Alexandria, Virginia 22313-1450

Art Unit: 3743

Examiner Kathryn Odland

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TECHNOLOGY CENTER R3700

## **DECLARATION UNDER 37 C.F.R. SECTION 1.131**

- I, Donald K. Jones, declare as follows:
- 1. I am a co-inventor of the invention disclosed and claimed in the above identified application.
- 2. I have a degree in material science and engineering. I have worked in the field of biomedical engineering, including embolization devices, for over seven years. I am an inventor in numerous patents relating to neurological devices.
- 3. It is my understand that U.S. Patent No. 6,280,457 to Wallace et al., filed June 4, 1999, has been cited by the Patent and Trademark Office in support of rejections of claims 1-4, 6-14, 16, 17, 20, and 27 of the above-identified application.
- 4. The invention of this application was made prior to June 4, 1999, the date of filing of U.S. Patent No. 6, 280,457. More specifically, the invention was made and completed, and actually reduced to practice, all in the United States of America, prior to June 4, 1999, as evidenced by the attached exhibits.

- 5. Exhibit A is a date-redacted copy of an invention record disclosure signed by Vladimir Mitelberg and me. Exhibit A reports on work performed by us and/or under our direction and control in the United States of America prior to June 4, 1999, in connection with making embolic coils for occluding the vasculature of a patient, which devices were made and reduced to practice before June 4, 1999.
- 6. With respect to Exhibit A (the invention record) referred to in paragraph 5 above, the photographs set forth in the last page of this invention record were taken by me of the roughened coils prior to submitting them for evaluation. The page having the number 028122 shows service requests. The picture on the bottom is a service request in which the coils were submitted for evaluation. Four photomicrographs were taken as indicated by the middle box and these four microphotographs were the results of the service requests. These photomicrographs are on the page of Exhibit A following the service requests. All of these photographs and service requests were taken and made prior to June 4, 1999.
- 7. Exhibit B are date-redacted copies of experiments performed on baboons, in connection with occluding the vasculature of the baboons, which experiments were performed before June 4, 1999.
- 8. The work referred in paragraph 7 above, included ex-vivo tests outside of the body using the baboon. A silicone tube was connected to the artery of the baboon. Blood flow was through the silicone tube and back to the baboon. In the silicone tube, aneurysms were formed on the tube itself. A delivery catheter was used to place roughened embolic coils inside of the aneurysms, with the help of a pusher mechanism. Live blood was run through the system and radioactive platelets accumulated on the

coils. The coils used were textured 5 mm. complex coils. By using a gamma camera imager, the radioactivity was measured. Non-textured coils were also used. It was found that there were greater amount of platelets on the roughened coils then on the non-roughened coils. From these experiments we were able to conclude that the introduction of the textured coils in the aneurysm would enhance platelet adhesion.

- 9. In view of my experience in biomedical engineering (including embolization devices) prior to June 4, 1999, I was confident that the vasculature of a patient could be successfully occluded by providing a plurality of embolic coils having a proximal portion that is held by the detachment portion and a distal portion, with the proximal portion that is held by the detachment portion being relatively smooth and the distal portion having a relatively textured surface. I found that the textured surface provides improved platelet adhesion compared to a non-textured surface, to promote clotting. As a result of the experiments, I was confident that the embolization device having a roughened surface was suitable for placement in a catheter for being conventionally implanted with an introducer having a detachment portion to provide improved platelet adhesion compared to a non-textured surface, to promote clotting. Accordingly, in my view, the invention was reduced to practice on a date prior to June 4, 1999, because I was confident that clinical versions of the prototype could be sterilized and clinically used with success to embolize aneurysms in patients.
- 10. I hereby declare that all statements made herein and of my own knowledge are true, and that all statements made on information and belief are believed to be true; and I further declare that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or

imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or patent issued therefrom.

Date: <u>5/11/09</u>

Donald K. Jones



DEPARTMENT

## **DESCRIPTIVE TITLE: Coil Surface Modification**

- I. INSTRUCTIONS: This form should be typed, except for the signatures and dates. Disclose only one invention on this Invention Disclosure form, and complete the entire form as fully as possible. Forward the completed form to the Legal Department, signed and dated by all inventors and two witnesses. Refer to this Invention Disclosure by the number assigned to it when receipt is acknowledged. Attach additional sheets if more space is required. Each original piece of paper must be signed and dated by every inventor and by each witness.
- II. ILLUSTRATION: Include a drawing, sketch, photograph, flow chart, or preferably an engineering quality printout of the invention.

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Name & Signature of Inventor(s):

Date

Witnesses

Date

EXHIBIT A

Rosald Plans

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III. EXPLANATION OF INVENTION: Describe the invention completely, including all essential elements. The invention is a surface modified embolization coil. The surface has been texture by abrasion or "sand blasting". Fifty-micron diameter alumina particles were used to texture the surface of the platinum tungsten wire used to form the coils. It is believed that the textured surface provides improved platelet adhesion thus promoting clotting and subsequent endothelialization. SEM micrographs and optical pictures of the textured vs. non-textured are attached. Testing using radiolabeled platelets was conducted to evaluate an ex vivo aneurysm model. In the model, aneurysms treated with textured coils were compared to aneurysms treated with non-textured coils. The textured coils showed an increase in the platelet deposition of about 50% over the non-textured coils.

IV. NOVEL FEATURES AND ADVANTAGES: What is new that was not previously known, and why is this important.

Other surface modification techniques such as coating or ion implantation require expensive and elaborate equipment to modify the coils which add an additional component. This method does not impart any new materials to the coil that would require new biocompatability testing and can be done inexpensively.

V. MODIFICATIONS: Describe all possible modifications or alternate embodiments.

VI. RELATED DOCUMENTS: List all known relevant art references (patents, publications, commercially available products, etc.) Please supply copies of the documents, if available.

Patents:

**Publications:** 

Signature of Inventor(s):

Date:

Witnesses:

Date:

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## ΫII. **INVENTORS:** Donald K. Jones First Inventor's Full name (Please type:) Date: Vladimir Mitelberg Second Inventor's Full Name (Please type): Signature: WITNESSES: This invention was disclosed to and understood by: Full Name of First Witness (Please type): E .: Cheng Full Name of Second Witness (Please type:) IX. ADDITIONAL INFORMATION: Invention is recorded on page(s): \_\_\_\_\_ of Notebook No.: \_\_ Earliest date: and place: CES thought of the present invention. First written description (date and present location): First sketch of the invention (date and present location): where first operating Earliest date: and place: \_ model was completed. Present location of model: Earliest date of use of the invention (actual or contemplated):

Earliest shipping date (actual or contemplated):



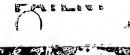
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## **Service Request**

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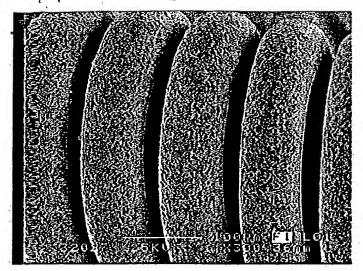


Figure 1-(233x) Sample with rough surface

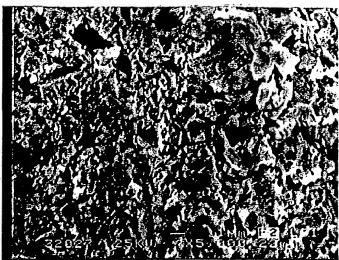


Figure 2-(3880x) Sample with rough surface

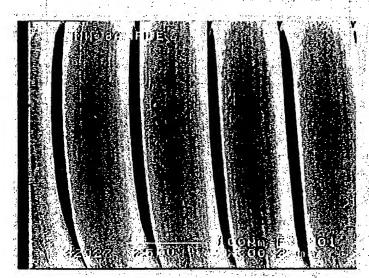


Figure 3-(233x) Sample "MW" with smooth surface.

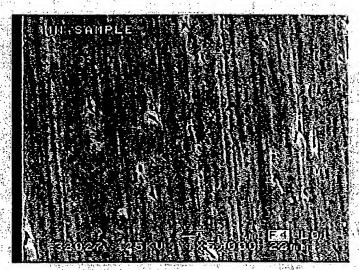
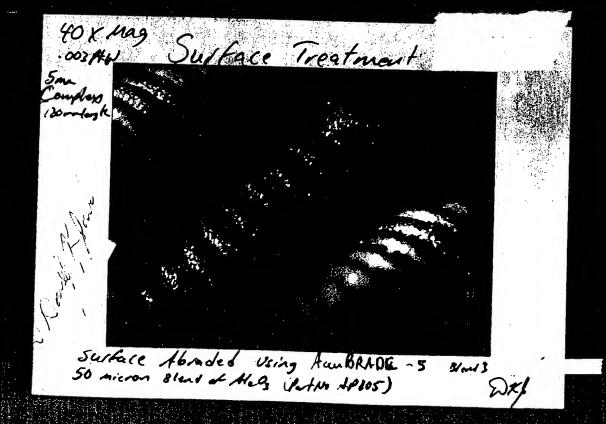


Figure 4-(3880x) Sample."MW" with smooth surface.

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	Aneurysm Run #7 textured 5mm dim. complex coils. Tail from Aneu. #1 extended 130mm. Tail from Aneu.#2 extended 180mm	CPM	31.00	87.00	120.00 82.00	104.00	87.00	331.00	366.00	362.00	442.00	520.00	640.00	580.00	440.00	612.00	708.00	644.00	698.00	788:00	820.00	964.00	950.00 856.00
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Data Partition   A341   Pit Cntr Pre   245   Whole Blood   Pit Cntr Post   204   Pit Cntr Post   42.109%   Volume (cc)   Pit Cntr Post   42.109%   Volume (cc)   Pit Cntr Post   42.109%   Pit Cntr Post   Pit C	0.26	372.00 0.000689	264.00	636	185		0.08	0.000689		641	751	35
Data Partition	0.23	330.00 0.000689	246.00	576	180		0.04	0.000689		538	592	30
Data Partition   A341   Pit Cnt Pre 1295   Whole Blood   Title   Camera   G E   WBC   11.5   Fraction   Hct Pre 145.40%   Fraction   Hct Post   42.40%   Fraction   Hct Post   42.10%   Volume (cc)   3   Energy   172   Flow (ml/min)   100/clamp   Bkg.CPM   1672   Bkg.CPM   1381   CPM   In-pits   1281.589   CPM   In-pits   In-pits   In-pits   In-pits   In-pits   In-pits	0.26	378.00 0.000589	240.00	618	175		0.04	0.000689		442	493	25
Data Partition   A341   Pit Cnt Pre   295   Whole Blood   Title   Pit Cnt Post   204   Piasma   Title   Pit Cnt Post   204   Pit Cnt Post   42.10%   Pit Cnt Post   Pit	0.23		00	566	170		0.01	0.000689		303	324	28
Data Partition   A341   Pit Cnt Pre 295   Whole Blood 11		- 1	00	584	165		-0.02	0.000689	-	240	215	15
Data Partition   A341   Pit Cnt Pre 1295   Whole Blood 11	0.23	328.00 0.000689	00	544	160		0.02	0.000689		168	190	10
Data Partition	0.21	304.00 0.000689	5	510	155		0.02	0.000689		150	184	C)
Data Partition		hrombus Standard	bkg	CPM	Min		Pits x10°	Standard	Thrombus:	٠.	CPM	Min
Data Partition		CPM		. :	Time				CPM	16X66	6x/2	÷.
Data Partition										RO	20	
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Data Partition			Blood		· 4 4.				· · · · · · · · · · · · · · · · · · ·	extended 1t	m Aneu.#2	Z. Iaii in
Data Partition A341 Pit Cnt Pre 295 Whole Blood Camera G E WBC 111.5 Fraction ROI (device) 8 x 10 Hct Pre 45.40% Volume (cc)			100/clamp	(ml/min)	Flo		Energy	meu.	1.25" from a	#1 stopped	from Aneu.	oils. Tail
Data Partition Camera  Camera  ROI (device)  Computer A3  Pit Cnt Pre 295  With Chit Post 204  Plasma Pit Cnt Post 204  Plasma  Pit Cnt Pre 245  Plasma  Pit Cnt Pre 245  Plasma  Plas	3	Volume (cc)	12.10%	Hct Post	٠	15%	Window		nm dim. co	textured 5r	Run #1 ur	neurysn
Data Partition A341 Pit Cnt Post 204 Plasma	92.8% 7.2%	Fraction	15.40%		•	8 × 10	l (device)	R		•	cripti n	tudy Des
Computer A3 PII Cnt P78 1285 Whole Blood	16014	Plasma	204	It Cnt Post	-10	A341	Partition	Data			•	Date
	121400	DOOLG BLOUAN	Cao	THE CHILDREN	1	3	Computer				्रम्मा । स्टार	

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